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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 18

Application Number: 09/246,468
Filing Date: February 9, 1999
Appellant(s): Rebek et al

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GROUP 2900

Thomas E. Northrup
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed January 10, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

As stated by appellant in the Brief, the After Final Response (Request for Reconsideration) filed September 11, 2001 was considered but was not deemed sufficient to overcome the rejections (this Response did not contain any claim amendments).

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 1-15 stand or fall together.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-15 are rejected under 35 U.S.C. 101 and 112 for lack of specific utility. These rejections (from prior Office action, Paper No. 11) are set forth below:

Claim Rejections - 35 USC § 101/112 - Lack of Specific Utility

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

According to the text of 35 USC sec. 101, an invention must be "useful". Our reviewing courts have applied the labels, "specific utility" (or "practical utility") to refer to this aspect of the

“useful invention” requirement of sec. 101. (Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980)). In Nelson, the Court characterized “specific utility” (or “practical utility”) as “a shorthand way of attributing real-world value to claimed subject matter. In other words[, the claimed subject matter will be deemed to have utility if one skilled in the art can use the] claimed discovery in a manner which provides some immediate benefit to the public.” (Id. at 856.)

The only utility disclosed for the instant compounds is that they can be used as core molecules for use in constructing a combinatorial library. These libraries are further screened to determine whether - or not - any of the compounds contained within the libraries possess some exploitable biological activity. See, for example, the instant specification, page 4, line 14 through page 5, line 2; page 6, lines 4-11; and page 13, line 12 through page 14, line 3. Therefore, the issue for the claimed compounds under this statute is whether the fact that the claimed compounds can be used to create combinatorial libraries that can be can be screened, without more, constitutes an “immediate benefit to the public”. The analysis proceeds on two levels. On a first level, an issue is whether any of the claimed compounds are of an immediate benefit to the public. On a second level, an issue is whether the claimed use of the compounds as core molecules for constructing a combinatorial library represents a specific asserted utility. As will be seen from the following discussion, the claimed compounds provide no immediate benefit to the public and the claimed use does not qualify as a specific asserted utility.

With respect to the individual compounds, it is clear that the specification discloses no specific exploitable biological (or other) activity for any of the compounds that would render them of an immediate benefit to the public. The specification suggests that libraries of such compounds be screened for such activity, but does not report that any of the compounds possess an exploitable activity.¹ On the contrary, whether any of the compounds possess such an activity is entirely speculative. Indeed, it is possible, according to the specification as a whole, that none of the compounds will turn out to have any useful activity. Applicants have left to others this burden of determining by means of screening whether any of the compounds will amount to more than mere objects of scientific inquiry². Therefore, as to the individual compounds, there is no disclosed specific utility.

On the second level of analysis, the claimed use of the compounds as core molecules for constructing a combinatorial library also would not provide an immediate benefit to the public as such is not a specific asserted utility. The specification states that the benefit that the libraries

¹ Had the specification taught that any of the compounds had a useful activity, then those compounds would be of immediate benefit to the public. The other compounds would then enjoy a rebuttable presumption that they also possess the specified activity. The burden would be on the USPTO to assert, by a preponderance of the evidence, that the proposed utility is not credible. MPEP 2107.

² Note, because the claimed invention is not supported by a specific asserted utility for the reasons just set forth, credibility cannot be assessed.

provide the public is their usefulness as “research tools.” See the specification, at page 13, lines 12-13, and elsewhere: “A combinatorial library of this invention is useful for rapidly generating and developing large numbers of drug candidate molecules.” While research tools have long been recognized as being patentable subject matter, there is also a well-recognized distinction between research tools and the objects of research. Thus, while telescopes, microscopes, gas chromatographs, screening assays, and the like, are examples of research tools that enjoy unquestioned utility (MPEP 2107(I) second column), chemical entities, with no disclosed (and no generally well known) useful activity do not.

Thus, one must distinguish between inventions that have a specifically identified utility and inventions whose specific utility requires further research to identify or reasonably confirm. The claimed compounds (and combinatorial libraries made therefrom) fall into this latter category. Giving them labels such as “research tool,” “intermediate” or “for research purposes” does not without more impart specific utility to the invention if, by such labels, it is meant that the invention is merely the object of further research. MPEP 2107(I), second column. As the claimed compounds (and the libraries made therefrom) are in practice objects of further research, they cannot fairly be characterized as “research tools” in the same sense as a microscope or gas chromatograph. Therefore, on the second level of analysis, the claimed compounds do not have a specific asserted utility.

In the absence of an asserted specific utility, the “useful” requirement may be established by reference to a well-established utility. MPEP 2107.01(II)(B). A “well established utility” is a “specific utility” which is well known, immediately apparent and implied by the specification based on the disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The claimed compounds are not supported by a well-established utility, however, because neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility would be well established for the compounds. Further, the compounds are not recognizable as analogous to compounds with a recognized pharmacological (or other) activity. In the absence of any data as to their activity, there is no basis upon which to base either a specific or a well-established utility.³ However, the following should be noted as it pertains to the art cited below.

³ Note that a “well established utility” cannot alternatively be based upon a “throw away” utility that one can dream up for an invention, or upon a utility that would obviously apply to virtually every member of a very general class of materials. If this were the case, any product or apparatus, including perpetual motion machines, would have a “well established utility” as landfill, an amusement device, a toy, or a paper weight, any carbon containing molecule would have a “well established utility” as a fuel since it can be burned, and any protein would have well established utilities such as manufacturing supplements for vitamins or food, as protein supplements for animal food, or as an animal poison if the protein is toxic. This is clearly not the intention of the statute.

The base structure of the claimed core compound (where R and R₁ = H) is well known in the art but has no well-established utility of its own, being as this compound has been used in a variety of other syntheses (for example, see US 3,071,591, cited previously). It should be noted that the prior art teaches using this compound to create compounds that have completely different substituent patterns than those set forth in claims 3 and 5-15 and therefore would not suggest that the claimed compounds had similar activity to those compounds known in the prior art. Additionally, the core compound and several variants are known in the art as starting materials for the creation of synthetic host molecules (for example, see Smeets et al, cited previously). These synthetic host molecules represent research tools for studying host-guest chemistry, which also does not constitute a patentable well-established utility.

Claims 1-15 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(11) Response to Argument

Rejection under 35 USC 101

Appellant argues that the examiner “confuses the claimed core molecules of the subject invention with the individual members of the combinatorial library made using the core

molecules” and that the “utility of the library members is **NOT** the issue” (Brief, page 3, emphasis in original). As set forth in the rejection:

The only utility disclosed for the instant compounds is that they can be used as core molecules for use in constructing a combinatorial library. These libraries are further screened to determine whether - or not - any of the compounds contained within the libraries possess some exploitable biological activity.

The examiner’s position is that making a combinatorial library is the asserted use of the claimed compounds. Thus the utility of the library members made is therefrom is critical. Moreover, Appellant states on page 4 of the Brief that “the present invention provides a core molecule for use in constructing a combinatorial library” (emphasis in original).

Appellant also states that “the core molecules of this invention are not intermediate precursors to the library members” and that “the series of cases dealing with utility of chemical intermediates is inapposite to the present invention” (Brief, pages 3-4). The examiner respectfully disagrees. As stated by appellant “the present invention provides a core molecule for use in constructing a combinatorial library”, thus the core molecule is indeed a chemical intermediate in the synthesis of a combinatorial library. As set forth in MPEP 2107.01 and discussed in the rejection above, a “substantial utility” defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a “substantial utility” define a “real world” context of use. An assay that

measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a “real world” context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use and, therefore, do not define “substantial utilities”:

- (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
- (B) A method of treating an unspecified disease or condition;
- (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
- (D) A method of making a material that itself has no specific, substantial, and credible utility; and
- (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

The examiner’s position is that the instantly claimed compounds *would* fall into the category of (E) above and thus would require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use.

Appellant also argues that the distinction made by the examiner between objects of research and research tools is a “distinction without a difference” (Brief, page 4). The examiner respectfully disagrees. As stated in the rejection, “while telescopes, microscopes, gas chromatographs, screening assays, and the like, are examples of research tools that enjoy unquestioned utility (MPEP 2107(I) second column), chemical entities, with no disclosed (and no generally well known) useful activity do not.”

Also, see MPEP 2107.01: Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between *inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.* (emphasis added)

As stated in the rejection, the asserted utility in the instant case (core molecule for use in constructing a combinatorial library) requires further research to identify or reasonably confirm. An asserted utility must be specific, not general. The statement of the utility must fully and clearly explain why the applicant believes the invention is useful. In the instant case, the Appellants have left to others the burden of determining by means of screening (for some undisclosed activity) whether any of the compounds of the combinatorial library made using the claimed core compounds will amount to more than mere objects of scientific inquiry. Therefore, as to the individual core compounds, there is no disclosed specific utility.

Appellants point to the specification page 17, line 8 and continuing to page 20, line 13 for a “detailed description of the utility of the present invention” (Brief, page 4). To reiterate, the examiner’s position is that this asserted utility is not specific and substantial.

See also MPEP 2107.02 (cited in part below):

A statement of specific and substantial utility should fully and clearly explain why the applicant believes the invention is useful. Such statements will usually explain the purpose of or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful. Except where an invention has a well-established utility, the failure of an applicant to specifically identify why an invention is believed to be useful renders the claimed invention deficient under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph. In such cases, the applicant has failed to identify a "specific and substantial utility" for the claimed invention.

For example, a statement that a composition has an unspecified "biological activity" or that does not explain why a composition with that activity is believed to be useful fails to set forth a "specific and substantial utility." *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful insufficient under 35 U.S.C. 101); *In re Ziegler*, 992 F.2d 1197, 1201, 26 USPQ2d 1600, 1604 (Fed. Cir. 1993) (disclosure that composition is "plastic-like" and can form "films" not sufficient to identify specific and substantial utility for invention); *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) (indication that compound is "biologically active" or has "biological properties" insufficient standing alone).

Rejection under 35 USC 112

Appellant argues (Brief, pages 5-6) that one of ordinary skill would know how to use the invention and points to several places in the specification which teach how to make the claimed compound and "how to use the claimed compounds as a soluble scaffold (core molecule) for constructing and deconvoluting a combinatorial library" (Brief, page 5). First, the question at hand is not how to make the compounds but how to use them. The cited portions of the specification (e.g. pages 15-20) do not contain any teachings whatsoever as to the specific nature of the libraries to be made and their activity. The issue remains that the examiner deems the asserted utility of the claimed compounds as core molecules for use in

constructing a combinatorial library to **not** meet the requirements of a specific and substantial utility.

Also, Appellant is pointed to MPEP 2107.01(IV):

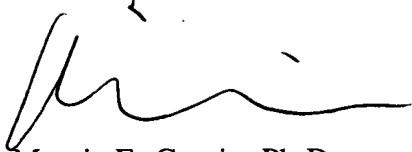
A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) ("If such compositions are in fact useless, appellant's specification cannot have taught how to use them."). Courts have also cast the 35 U.S.C. 101 /35 U.S.C. 112 relationship such that 35 U.S.C. 112 presupposes compliance with 35 U.S.C. 101. See *In re Ziegler*, 992 F.2d 1197, 1200-1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. 101 that the specification disclose as a matter of fact a practical utility for the invention. ... If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112."); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) ("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."). For example, the Federal Circuit noted, "[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph.

For the above reasons, it is believed that the rejections should be sustained.

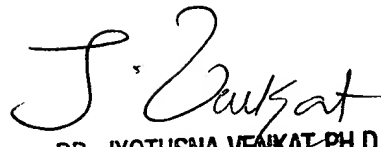
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Respectfully submitted,

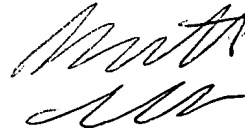


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